

**WHAT IS CLAIMED IS:**

1. A glycosaminoglycan measuring device, comprising:
  - a sample entry port adapted to accept a bodily fluid sample;
  - a glycosaminoglycan separation cartridge coupled to the
  - 5 sample entry port and adapted to separate glycosaminoglycans from interfering substances in the sample; and
  - a detection apparatus comprising a detection chamber coupled to the glycosaminoglycan separation cartridge and adapted to detect the separated glycosaminoglycans.
- 10 2. The glycosaminoglycan measuring device of claim 1, further including a reagent storage device coupled to the glycosaminoglycan separation cartridge and adapted to store reagents for delivery to the glycosaminoglycan separation cartridge.
- 15 3. The glycosaminoglycan measuring device of claim 2, further including a first pump coupled to the glycosaminoglycan separation cartridge and adapted to pump fluids into the separation cartridge.
- 20 4. The glycosaminoglycan measuring device of claim 3, further including a second pump coupled to the detection apparatus and adapted to pump fluids to the detection chamber.
- 25 5. The glycosaminoglycan measuring device of claim 4, further including a controller adapted to control the operation of the first and second pumps.
6. The glycosaminoglycan measuring device of claim 5, wherein the controller includes a processor, a computer readable memory, and a routine stored

on the computer readable memory and adapted to be executed on the processor to control the operation of the first and second pumps.

7. The glycosaminoglycan measuring device of claim 1, further  
5 including a user interface device operably connected to the detection apparatus, the user interface device including a user interface, a processor, a computer readable memory and a routine stored on the computer readable memory and adapted to be executed on the processor to analyze the output of the detection apparatus and display results of analysis to a user via the user interface.

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8. The glycosaminoglycan measuring device of claim 7, wherein  
the user interface is adapted to prompt a user to log in to the device, initialize the device, enter patient information, prime the device, start the routine, clean the device, reset a cycle counter, enter comments, enter known standard solutions, calculate  
15 standard curves, calculate amounts of glycosaminoglycans based on a standard curve, record user actions, or shutdown the device.

9. The glycosaminoglycan measuring device of claim 1, wherein  
the glycosaminoglycan separation cartridge comprises an ion exchange resin.

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10. The glycosaminoglycan measuring device of claim 1, wherein  
the detection apparatus is a spectrophotometer.

11. The glycosaminoglycan measuring device of claim 1, further  
25 comprising a temperature controller operably connected to the detection apparatus.

12. The glycosaminoglycan measuring device of claim 11, wherein  
the temperature controller is a thermofoil heater.

13. The glycosaminoglycan measuring device of claim 1, further comprising:

a first fluid passageway coupled between the sample entry port and the glycosaminoglycan separation cartridge and adapted to deliver the sample  
5 from the sample entry port to the glycosaminoglycan separation cartridge; and

a second fluid passageway coupled between the glycosaminoglycan separation cartridge and the detection chamber and adapted to deliver the separated glycosaminoglycans from the glycosaminoglycan separation cartridge to the detection chamber.

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14. The glycosaminoglycan measuring device of claim 13, further comprising one or more valves adapted to control liquid flow in one or more of the fluid passageways.

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15. A glycosaminoglycan measuring device comprising:

a sample entry port coupled to a first transport line;

a first reagent container coupled to a second transport line;

a second reagent container coupled to a third transport line;

20 more transport lines;

a waste discharging port coupled to a fourth transport line;

a detecting reagent container coupled to a fifth transport line;

a pump operably connected to one or more of the transport lines; and

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a detection apparatus operably connected to the device.

16. A device according to claim 15, further comprising a reagent measuring loop in communication with one or more transport lines.

17. A device according to claim 15, further comprising a gas entry port coupled to one or more transport lines.

5 18. A device according to claim 15, further comprising a cleaning solution container coupled to a sixth transport line.

19. A device according to claim 15, further comprising a transport line adapted to mix liquids.

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20. A device according to claim 15, wherein the glycosaminoglycan separation cartridge comprises an ion exchange resin.

15 21. A device according to claim 15, wherein the detection apparatus is a spectrophotometer.

22. A device according to claim 15, further comprising a temperature controller operably connected to the detection apparatus.

20 23. A device according to claim 15, further comprising a valve coupled to one or more transport lines and adapted to direct liquid flow.

25 24. A glycosaminoglycan measuring device comprising a sample entry port, separator means for substantially separating glycosaminoglycans from a sample delivered at the sample entry port to produce separated glycosaminoglycans, and detection means for detecting the separated glycosaminoglycans.

25. A method of measuring glycosaminoglycans in a body fluid sample, comprising the steps of:

(a) automatically delivering a portion of the sample to a glycosaminoglycan separation cartridge;

5 (b) separating glycosaminoglycans from interfering substances using the glycosaminoglycan separation cartridge;

(c) automatically delivering the separated glycosaminoglycans to a detection apparatus;

10 (d) combining a detection reagent with the separated glycosaminoglycans;

and

(e) detecting the amount of separated glycosaminoglycans by detecting the amount of detection reagent bound to the separated glycosaminoglycans.

15 26. The method of claim 25, further comprising the step of analyzing an output of the detection apparatus and displaying the analyzed output to a user.

20 27. The method of claim 25, wherein automatic delivery occurs in response to user input.

28. A method according to claim 25, wherein step (b) comprises the steps of:

25 binding glycosaminoglycans to a solid phase;  
removing interfering substances; and  
eluting glycosaminoglycans from the solid phase.

29. A method according to claim 28, wherein the removing step is contacting the solid phase with a buffered solution comprising Na<sup>+</sup> at a concentration ranging from 350mM to 450mM.

5                   30. A method according to claim 28, wherein the eluting step is contacting the solid phase with a buffered solution comprising Na<sup>+</sup> at a concentration ranging from 700 mM to 1500mM.

10                   31. A method according to claim 25, wherein the body fluid sample is selected from the group consisting of whole blood, plasma, serum, urine, cerebrospinal fluid, pleural fluid, extracts of tissue biopsies, saliva, semen, stool, sputum, tears, and mucus.

15                   32. A method according to claim 25, wherein the body fluid sample is blood or urine.

20                   33. A method according to claim 25, wherein the separated glycosaminoglycans include glycosaminoglycans selected from the group consisting of chondroitin sulfates, dermatan sulfates, keratan sulfates, heparan sulfates, heparin sulfates, and heparin.

34. A method according to claim 25, wherein the separated glycosaminoglycans include heparin.

25                   35. A method according to claim 25, wherein the glycosaminoglycan capturing cartridge includes an ion exchange resin.

36. A method according to claim 25 wherein the detection reagent is a metachromic dye that specifically binds glycosaminoglycans.

37. A method according to claim 25, wherein the detection reagent is selected from the group consisting of alcian blue, azure A, azure B, dimethylmethylen blue, fuchsin, acridine orange, proflavine, neutral red, and brilliant  
5 cresyl blue.

38. A method according to claim 25, wherein the detection reagent is dimethylmethylen blue (DMMB).

10 39. A method according to claim 25, wherein the detection apparatus is a spectrophotometer.

40. A method according to claim 25, further comprising the use of software designed to quantify the amount of glycosaminoglycans present based on  
15 detecting the detection reagent bound to the separated glycosaminoglycans.

41. A method according to claim 25, wherein step (e) occurs at a regulated temperature.

20 42. The method according to claim 25, further comprising the step of adding one or more glycosaminoglycan-specific degrading enzymes to the sample before step (a).

25 43. A method according to claim 42, wherein the glycosaminoglycan-specific degrading enzyme is selected from the group consisting of chondroitinase B, chondroitinase AB, heparinase, heparitanase, heparitanase I, heparitanase II, keratanase,  $\alpha$ -L-iduronidase, iduronate sulfatase, Heparan N-sulfatase, N-acetylglucosaminidase,  $\alpha$ -glucosamine-N-acetyltransferase,  $\alpha$ -glucosamine-6-

sulfatase, N-acetylgalactosamine-6-sulfatase, B-galactosidase, N-acetylgalactosamine-4-sulfatase, and B-glucuronidase.

5 44. A method according to claim 43, wherein the glycosaminoglycan-specific degrading enzyme is chondroitinase B.

45. A method according to claim 25, wherein step (e) comprises the step of shining light at a wavelength of about 526 nm  $\pm$  5nm at the separated glycosaminoglycans.

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46. A method according to claim 25, wherein step (e) comprises the step of shining light at a wavelength of about 592 nm  $\pm$  5nm at the separated glycosaminoglycans.

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47. A method according to claim 25, performed substantially concurrent with heparin therapy.

48. A method according to claim 25, performed for the purpose of monitoring heparin therapy.

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49. A method according to claim 25, performed for the purpose of measuring endogenous heparin levels.

25 50. A method according to claim 25, performed for the purpose of screening newborns, infants, or children for disorders associated with abnormal glycosaminoglycan concentration levels.

51. A method according to claim 25, performed for the purpose of diagnosing mucopolysaccharidoses.

52. A method of using the device of claim 1 for monitoring the amount of heparin in a patient receiving heparin therapy.

53. A method of using the device of claim 1 for measuring endogenous heparin levels.

54. A method of using the device of claim 1 for the purpose of screening newborns, infants, or children for disorders associated with abnormal glycosaminoglycan concentration levels.

55. A method of using the device of claim 1 for the purpose of diagnosing mucopolysaccharidoses.

56. A kit comprising instructions for using a device according to claim 1 and one or more reagents for use in a device according to claim 1.

57. A kit comprising instructions for using a device according to claim 1 and one or more standards of known glycosaminoglycan concentration.